6-11-01

PCT

FORM PTO-1390 (REV 11-2000) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: QMT-1 US

JC17 Rec'd PCT/PTO 09 JUN 2001

U.S. APPLICATION NO. (If known, see 37 CFR 1.5): 60/111,472 09/857906

INTERNATIONAL APPLICATION NO.:	INTERNATIONAL FILING DATE:	PRIORITY DATE CLAIMED
PCT/US99/29091	12/8/1999	12/9/1998

TITLE OF INVENTION: INTRINSICALLY BACTERIAL ABSORBENT DRESSING AND METHOD OF FABRICATION

APPLICANT(S) FOR DO/EO/US Quick-Med Technologies, Inc.,

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [x] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [ ] This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. [x] The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. [x] A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
   a. [x] is attached hereto (required only if not communicated by the International Bureau).
   b. [x] has been communicated by the International Bureau.
   c. [x] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [x] An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).
   a. [x] is attached hereto.
   b. [ ] has been previously submitted under 35 U.S.C. 154(d)(4).
7. [x] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [x] are attached hereto (required only if not communicated by the International Bureau).
   b. [ ] have been communicated by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.
8. [ ] An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [ ] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording.
13. [ ] A FIRST preliminary amendment.
14. [ ] A SECOND or SUBSEQUENT preliminary amendment.
15. [ ] A substitute specification.
16. [ ] A change of power of attorney and/or address letter.
17. [ ] A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 – 1.825.
18. [ ] A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. [ ] A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. [ ] Other items or information:

I hereby certify that this correspondence is being deposited with the US Post Office with sufficient postage in an Express Mail envelope, with Express Mail no. ET321924551US, addressed to: Assistant Commissioner for Patents Washington, D.C. 20231 on 6-8-2001.

Timothy H. Van Dyke, Reg. No. 43,218

U.S. APPLICATION NO (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
60/111,472 09/857906	PCT/US99/29091	QMT-1 US

21. [X] The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :

	CALCULATIONS PTO USE
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1000.00**	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$860.00**	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445 (a)(2)) paid to USPTO **$710.00**	
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$690.00**	
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**	
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 690.00
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ] 20 [x] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ 130.00

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	$
Total claims	8	0	X **$18.00**	$ 0.00
Independent claims	2	0	X **$80.00**	$ 0.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$270.00**	$ 0.00
TOTAL OF ABOVE CALCULATIONS =				$ 820.00
[x] Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by ½.			+	$ 410.00
SUBTOTAL =				$ 410.00
Processing fee of **$130.00** for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.49(f)).				$ 0.00
TOTAL NATIONAL FEE =				$ 410.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$ 0.00
TOTAL FEES ENCLOSED =				$ 410.00
			Amount to be: refunded	$
			charged	$

a. [X] A check in the amount of $ 410.00 to cover the above fees is enclosed.

b. [ ] Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [ ] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. _____. A duplicate copy of this sheet is enclosed.

d. [ ] Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO

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43218
REGISTRATION NUMBER

Intrinsically Bactericidal Absorbent Dressing and Method of Fabrication

Field of the Invention

This invention relates generally to absorbent dressings, and more particularly highly-absorbent synthetic polymer dressings having antimicrobial agents attached thereto.

Background of the Invention

Bacterial growth in absorbent dressings for wounds, urinary incontinence diapers, and menstruation pads can lead to serious medical complications as well as social difficulties. For example, bacterial growth in urinary incontinence diapers or menstruation pads usually produces strong, unpleasant odors that are socially unacceptable and can cause persons to alter their lifestyle. Conventional absorbent pads for urinary incontinence and menstruation are not inherently bactericidal. Consequently, the only way to avoid growth of bacteria in the absorbent dressings is to change them at frequent intervals, even if the absorbent capacity of the pad has not been reached. In the area of wound dressings, bacterial contamination of acute wounds and infection of chronic skin wounds are major clinical problems that can result in significant morbidity and, in severe cases, mortality. Conventionally, wound dressings have been designed to absorb wound fluids and yet provide a moist environment for promoting wound healing. However, such moist environments create a nutrient rich reservoir for bacterial growth in the dressing. Bacteria growing in the dressing can be shed back into the wound, increasing the risk of wound infection, or response to toxins, and producing strong, foul odors.

In an effort to address these problems, antibiotics or chemical disinfectants are frequently applied topically to wounds prior to covering the wound with a dressing.

Alternatively, topical agents are sometimes applied directly to the surface of the dressing. To control foul odors, some known dressings incorporate charcoal powder to absorb molecules generating the foul odor. For some applications, topical application of antibacterial agents is not desirable. For instance, bactericidal agents applied topically to wound dressings have a tendency to seep into the wound being treated. Furthermore, many antimicrobial drugs, such as iodine, are cytotoxic and will retard wound healing if used repetitively or at high concentrations.

A composition comprising a superabsorbent polymer having a monolayer (or near monolayer) of silane antimicrobial agent in a covalent bonding relationship with the base polymer is disclosed in U.S. Patent No. 5,045,322. The composition may be in the form of flakes, strips, powders, filaments, fibers or films, and may be applied to a substrate in the form of a coating. The aforementioned composition is less apt to enter a wound vis-a-vis conventional topical treatment systems. In that respect, the disclosed composition provides an improvement over conventional topical treatment systems. However, silanes contain siloxane bonds which can be cleaved by acids and bases produced by infection or bacterial growth. In turn, these reactions may weaken or destroy bonds between the silane antimicrobial agent and the underlying polymer. Consequently, antimicrobial agent may seep into a wound and retard wound healing.

The need exists for an improved antimicrobial dressing composition having an antimicrobial agent which can be maintained securely attached to a superabsorbent polymer upon exposure to acids and bases produced by infection and bacterial growth. In addition to reducing the propensity for detachment of the antimicrobial agent, it would be desirable to provide a surface area enhanced dressing structure for increasing the effectiveness of the antimicrobial agent.

Summary of the Invention

It is an object of the present invention to provide an inherently bactericidal superabsorbant dressing having an enhanced surface area.

It is another object of the present invention to provide an inherently bactericidal superabsorbant dressing having an improved bactericidal attachment structure that resists degradation upon exposure to acids or bases produced, for instance, during bacterial growth.

These and other objects are achieved by the inherently bactericidal polymer composition of the present invention. In the preferred embodiment, the composition comprises a polymer matrix having quaternary ammonium groups tethered to its surface through non-siloxane bonds. The surface area of the polymer matrix is enhanced, for instance, by electrostatically spinning a fiber-forming synthetic polymer to form a frayed fiber or filament. Alternatively, the polymer solution can be wet- or dry-spun to create a roughened fiber surface by controlling the choice of solvent and the polymer solution temperature. Additional surface area enhancement is provided by tethering molecular chains of quaternary ammonium pendent groups to the surface of the polymer matrix. Tethering may be accomplished by known techniques such as grafting and selective adsorption.

In an alternate embodiment of the invention, non-ionic bactericidal molecules are coupled to the surface of the polymer matrix, in lieu of ionically-charged molecules. Ionically-charged molecules are prone to being neutralized upon encountering oppositely-charged molecules. For instance, positively-charged quaternary ammonium groups may be neutralized by negatively-charged chloride ions present in physiological fluids. In instances were such neutralization is significant enough to reduce the bactericidal properties of the dressing below an acceptable level, non-ionic surface groups may be preferable.

Detailed Description of the Preferred Embodiments

A novel antibacterial polymer composition is fabricated to have an enhanced surface area and superabsorbent capacity for biological fluids, including urine, blood, and wound exudate.

In the preferred embodiment of the present invention, the composition includes a polymer matrix having quaternary ammonium compounds attached to the surface of the polymer matrix. The polymer matrix is comprised of a plurality of hydrophilic fibers or filaments which can be fabricated in any suitable manner. For example, suitable fibers or filaments can be fabricated by wet- or dry-spinning a fiber-forming synthetic polymer from a spinning solvent. The resulting polymer has superabsorbent capacity. Generally, polymers capable of absorbing from about thirty to sixty grams of water per gram of polymer are considered to be superabsorbent. Examples of superabsorbent polymers which can be fabricated in this manner include polyacrylic acids, polyethylene oxides and polyvinyl alcohols. For example, methods for spinning polyethylene oxide using acetone solvent are well known.

Significantly, the polymer matrix is fabricated to have an enhanced surface area. Enhancing the surface area of the polymer matrix results in improved absorption of biological fluids, and increases the availability of sites for attachment of the antimicrobial quaternary ammonium compounds. A corresponding increase in the quantity and density of antimicrobial sites, in turn, enhances the efficacy of the composition in killing organisms such as bacteria and viruses.

It may occur to one skilled in the art of polymer science that a variety of methods are available for accomplishing surface area modification. Preferably, surface area enhancement is accomplished by a modified spinning or casting method. For instance, electrostatic spinning is a modified spinning technique which results in fraying of the fiber as it exits the spinerette. Alternatively, a polymer solution can be wet- or dry-spun to create a roughened fiber surface by controlling the solvent type and the polymer solution temperature. This technology is well known and has been applied, for example, in the manufacture of asymmetric membranes having roughened pores for dialysis. The size of the roughened pores is primarily controlled

by the speed of precipitation which, in turn, is controlled by solvent interaction parameters, temperature, etc.

The surface area of the polymer composition is further enhanced by tethering chains of antimicrobial groups to the outer surface of the individual polymer fibers. Preferably, molecular chains of quaternary ammonium pendent groups are fabricated to have at least one end adapted for attachment to a fiber surface. For instance, surface grafting may be accomplished by creating surface free radicals as initiation sites from peroxide generation (ozone or microwave). Alternatively, surface attachment of an interpenetrating network may be achieved using a monomer which swells the substrate polymer. The incorporation of tethered antimicrobial chains has the further benefit of enhancing the functionality of the composition. In particular, the tethered antimicrobial chains extend into the particular biological solution to bind to harmful bacterial and viral organisms. In contrast to known dressing compositions in which a monolayer (or near monolayer) of bactericidal compound is directly attached to a fiber surface, the chain structures of the present invention, which function like arms extending outwardly from the fiber surface, more effectively bind the antimicrobial sites to harmful organisms. Preferably, tethering is accomplished by grafting the antimicrobial chains directly to the matrix surface, or by selective adsorption of a copolymer to the matrix surface.

Grafting techniques are well known in the art. For example, quaternary ammonium compound grafting using the monomer trimethylammonium ethyl methacrylate to graft polymerize to a modified polyethylene surface is described by Yahaioui (Master's Thesis, University of Florida, 1986). Yahioui describes a grafting technique in which a plasma discharge is used to create free radicals which initiate polymerization of appropriate monomers. Selective adsorption of appropriate block copolymers can also be used.

In contrast to known compositions in which an antimicrobial structure is achieved by covalently bonding silane groups to the surface of the base polymer, the present invention incorporates a chemical structure which is based on polymerization (i.e., surface grafting) of monomers containing all carbon-carbon, carbon-oxygen and carbon-nitrogen main bonds, such as the dialkly, diallyl, quaternary ammonium compounds. Consequently, the composition of

the present invention results in a structure which is less prone to reacting with acids and bases produced by bacterial growth. As previously mentioned, such reactions can degrade the attachment between the matrix and antimicrobial groups. In instances where the composition is applied to a wound dressing, such degradation could result in antimicrobial agents detaching from the polymer matrix and entering a wound site. In some cases, this can have the deleterious effect of retarding wound healing.

In an alternate embodiment of the present invention, anionic antibactericidal groups are immobilized on the surface of a superabsorbant dressing to improve the antibactericidal efficacy of the dressing. The positive charge associated with quaternary ammonium groups, for example, can be neutralized by negative ions, such as chloride ions present in physiological fluids such as urine and plasma. For applications where the degree of neutralization will significantly reduce the effectiveness of the antibactericidal agent, anionic surface groups can be substituted for quaternary ammonium groups. Examples of chemical compounds that can be used to produce immobilized anionic surface groups include Triton-100, Tween 20 and deoxycholate. For instance, Triton-100 contains a free hydroxyl group which can be derivatized into a good leaving group, such as tosyl or chloride, and subsequently reacted with a base-treated polymer, such as methyl cellulose, to yield a surface immobilized non-ionic surfactant

Dimethyldiallyl ammonium chloride is one example of a suitable monomer which may be used with the present invention. This monomer, commonly referred to as DMDAC or DADMAC, is used in the fabrication of commercial flocculating polymers. Modifications of trialkyl(p-vinylbenzyl) ammonium chloride or the p-trialkylaminoethyl styrene monomers are also suitable. One such example is trimethyl(p-vinyl benzyl) ammonium chloride; the methyl groups of this monomer can be replaced by other alkyl groups to impart desired properties. Alternatively, methacrylate-based monomers may be used; however, they may suffer from hydrolytic instability under acidic and basic conditions in a fashion similar to the silane-based treatments of the prior art. Consequently, methacrylate-based monomers are not preferred.

While the preferred embodiments of the invention have been illustrated and described, it will be clear that the invention is not so limited. Numerous modifications, changes,

variations, substitutions and equivalents will occur to those skilled in the art without departing from the spirit and scope of the present invention as described in the claims.

We claim:

1. A dressing for absorbing biological fluids, comprising:

a superabsorbent polymer matrix having an enhanced surface area; and

a plurality of antimicrobial compounds coupled by non-siloxane bonds to said polymer matrix.

2. A dressing as recited in claim 1, wherein said plurality of antimicrobial compounds comprise quaternary ammonium compounds.

3. A dressing as recited in claim 1, wherein said antimicrobial compounds comprise chain-like structures tethered at one end to said polymer matrix.

4. A dressing as recited in claim 1, wherein said plurality of antimicrobial compounds are non-ionic compounds.

5. A dressing as recited in claim 1, wherein said dressing comprises a sanitary pad.

6. A dressing as recited in claim 1, wherein said dressing comprises a tampon.

7. A dressing as recited in claim 1, wherein said dressing comprises a bandage.

8. A method for fabricating an intrinsically antimicrobial absorbent dressing, comprising the steps of:

forming a superabsorbent synthetic polymer matrix having an enhanced surface area; and

attaching a plurality of antimicrobial compounds to the enhanced surface area of said polymer matrix.

PATENT APPLICATION

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION — **ATTORNEY DOCKET NO. OMT-1R US**

As a below named inventor, I hereby declare that:
My residence/post office address and citizenship are as stated below next to my name;
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:
INTRINSICALLY BACTERIAL ABSORBENT DRESSING AND METHOD OF FABRICATION
the specification of which is attached hereto unless the following box is checked:

(X) was filed on 6/9/2001 as US Application Serial No. 09/857,906 or PCT International Application Number PCT/US99/29091 and was amended on _____ (if applicable).

I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR 1.56.

Foreign Application(s) and/or Claim of Foreign Priority
I hereby claim foreign priority benefits under Title 35, United States Code Section 119 of any foreign application(s) for patent or inventor(s) certificate listed below and have also identified below any foreign application for patent or inventor(s) certificate having a filing date before that of the application on which priority is claimed:

COUNTRY	APPLICATION NUMBER	DATE FILED	PRIORITY CLAIMED UNDER 35 U.S.C. 119
PCT	PCT/US99/29091	12/8/1999	YES:___ NO:___
			YES:___ NO:___

Provisional Application
I hereby claim the benefit under Title 35, United States Code Section 119(e) of any United States provisional application(s) listed below:

APPLICATION SERIAL NUMBER	FILING DATE
60/111,472	12/9/1998

U.S. Priority Claim
I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION SERIAL NUMBER	FILING DATE	STATUS(patented/pending/abandoned)

POWER OF ATTORNEY:
As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) listed below to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Timothy H. Van Dyke, Reg. No. 43218

Send Correspondence to:	Direct Telephone Calls To:
Timothy H. Van Dyke Van Dyke & Associates, P.A. 1630 Hillcrest Street Orlando, Florida 32803	Timothy H. Van Dyke 407-228-0329

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

100

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DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION (continued) ATTORNEY DOCKET NO. QMT-1R US

280

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DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION (continued)

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DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION (continued)

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DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION (continued)

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